

# **EXHIBIT B**

NEW ENGLAND COMPOUNDING PHARMACY INC. PRODUCTS LIABILITY  
VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 1

1 UNITED STATES DISTRICT COURT

2 FOR THE DISTRICT OF MASSACHUSETTS

3

4 IN RE: NEW ENGLAND

5 COMPOUNDING PHARMACY, INC. MDL No. 2419

6 PRODUCTS LIABILITY LITIGATION Master Docket

7 1:13-md-02419-RWZ

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11 VIDEOTAPED DEPOSITION DUCES TECUM

12 OF RITU T. BHAMBHANI, M.D.

13

14

15 Wednesday, February 10, 2016

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23 Reported by: Lori J. Goodin, RPR, CLR, CRR,

24 Realtime Systems Administrator

25 Assignment No. 26236



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Page 2

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4           The deposition of RITU T. BHAMBHANI, M.D.,  
5 was convened on Wednesday, February 10, 2016,  
6 commencing at 10:01 a.m., at the offices of

7

8           PESSIN KATZ LAW  
9           Suite 400  
10          901 Dulaney Valley Road  
11          Towson, Maryland 21204

12

13 before Lori J. Goodin, Registered Professional  
14 Reporter, Certified LiveNote Reporter, Certified  
15 Realtime Reporter, Realtime Systems  
16 Administrator, and Notary Public in and for the  
17 State of Maryland.

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Page 3

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Page 4

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15 Meeko Goodhill, videographer  
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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 5

CONTENTS		
EXAMINATION BY	PAGE	
Mr. Roth	8	
EXHIBITS		
NO.	DESCRIPTION	PAGE
7	Exhibit 1051 Answers to PSC's first set of Interrogatories	9
9	Exhibit 1052 Responses to PSC's request for Production of documents	9
11	Exhibit 1053 Responses to Steering Committee Revised subpoena request	9
13	Exhibit 1054 CV of Dr. Ritu Bhambhani	23
14	Exhibit 1055 Earlier version of CV of Dr. Ritu Bhambhani	31
16	Exhibit 1056 Current Policy and Procedure Manual and organizational chart	46
18	Exhibit 1057 Salesman Andrew Howden's card	118
19	Exhibit 1058 Order form used by Box Hill for NECC, Bates 000011	118
21	Exhibit 1059 NECC prescription order form of 9/21/2012, Bates 13	131
23	Exhibit 1060 NECC prescription order form of 9/24/2012	137
25	Exhibit 1061 NECC invoice for 9/25 order	140



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 6

EXHIBITS CONTINUED		
NO.	DESCRIPTION	PAGE
3	Exhibit 1062 Packing list from NECC for 9/24/2012 order	141
5	Exhibit 1063 Packing list from NECC for 8/13/2012, Bates 10	142
7	Exhibit 1064 Form from Department of Health signed by Dr. Bhambhani, 10/6	157
9	Exhibit 1065 Procedure notes of Dr. Bhambhani 201 for Ms. Rozek's procedure at Box Hill Surgery Center, 8/31/2012	

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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016**

Page 7

## **PROCEEDINGS**

THE VIDEOGRAPHER: We are now on record. This is Tape Number 1 to the videotaped deposition of Dr. Ritu Bhamhani taken in the matter of In Re: New England Compounding Pharmacy, Inc., Products Liability Litigation.

8                   This deposition is being held at  
9 Pessin Katz Law, located at 901 Dulaney  
10 Valley Road, Suite 500, Towson, Maryland,  
11 21204, on Wednesday February 10th, 2016, at  
12 10:01 a.m.

13 My name is Meeko Goodhill and I am  
14 the videographer. The court reporter is Lori  
15 Goodin.

16 Counsel please introduce yourselves  
17 for the record, please.

18 MR. ROTH: My name is Harry Roth. I  
19 am from the firm of Cohen Placitella & Roth,  
20 and I represent the estate of Brenda Rozek.

21 MR. COREN: Michael Coren on behalf  
22 of multiple plaintiffs and the estate of  
23 Brenda Rozek.

24 MS. HOUSTON: Sharon Houston on  
25 behalf of multiple plaintiffs of the Law



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 8

1                   Offices of Peter Angelos.

2                   MS. KASPUTYS: Patricia Kasputys,  
3                   also with the Law Offices of Peter Angelos on  
4                   behalf of multiple plaintiffs.

5                   MS. STEINER: Catherine Steiner on  
6                   behalf of Dr. Ritu Bhambhani, Ritu Bhambhani,  
7                   M.D., LLC, and Box Hill Surgery Center.

8                   MR. KIRBY: Greg Kirby on behalf of  
9                   same Box Hill defendants.

10                  THE VIDEOGRAPHER: Court reporter  
11                  please swear in the witness and we can  
12                  proceed.

13                  RITU T. BHAMBHANI, M.D.,  
14                  a witness called for examination, having been  
15                  first duly sworn, was examined and testified as  
16                  follows:

17                  EXAMINATION

18                  BY MR. ROTH:

19                  Q. Good morning Dr. Bhambhani. How are  
20                  you?

21                  A. Good, thank you.

22                  Q. You understand that today I'm going  
23                  to question you generally about the practice at  
24                  Box Hill Surgical Center and the use of  
25                  compounded materials that were manufactured or



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 25

1           Q.     Okay. And your first job was at  
2 Chesapeake Perioperative Services?

3           A.     Correct.

4           Q.     You are, are you board certified in  
5 anesthesia and pain management?

6           A.     I am.

7           Q.     And, typically when we think of  
8 anesthesia, we think of somebody sitting in the  
9 operating room and delivering anesthesia during  
10 surgery or operative procedures.

11          Do you practice that type of  
12 anesthesia?

13          A.     I do.

14          Q.     Okay. And, can you tell me, is  
15 there a difference between the practice of that  
16 type of anesthesia and pain management?

17          A.     Probably a broad stroke difference  
18 would be anesthesia in general is done for  
19 patients who are undergoing a procedure. And the  
20 main role of the anesthesiologist is to have the  
21 patient undergo it without undue pain, so whether  
22 it is sedation or general anesthesia, where they  
23 are completely asleep.

24          Pain management on the other hand is  
25 where the focus is more in helping diagnose or



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 26

1 manage pain --

2 Q. Okay.

3 A. -- unrelated to surgical pain.

4 Q. Is the, your fellowship in pain  
5 management focuses on that latter type of  
6 treatment obviously.

7 A. Well, the fellowship itself, yes,  
8 you are right. The fellowship itself encompassed  
9 both acute post-operative pain. So, still  
10 somewhat related to the post-surgical period.  
11 That is just the nature of that particular  
12 fellowship program.

13 Q. Uh-huh.

14 A. But also a bigger emphasis was on  
15 non surgery related chronic pain.

16 Q. When you began your practice at  
17 anesthesiology and pain, I'm sorry, Chesapeake  
18 Perioperative Services, and if this is not the  
19 way to ask the question you will let me know, but  
20 how much of your time was spent in the operating  
21 room delivering anesthesia to surgical patients  
22 versus seeing patients for pain management?

23 A. So, I was brought on board by,  
24 mainly by, it was a group of practicing  
25 anesthesiologists and they had one physician who



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Page 27

1 was practicing both anesthesia and pain  
2 management.

3 And he wanted to continue doing both  
4 and the case load for pain management was, I  
5 guess, increasing to the point where he felt that  
6 the group needed to bring on another physician  
7 who could see the chronic pain management  
8 patients.

9 So, when I first started, it was a  
10 gradual process. I was there for just a little  
11 less than three years.

12 So, when I first started, he himself  
13 was doing, I think two, maybe two and a half days  
14 of pain, and anesthesia in the operating rooms  
15 the rest of the time.

16 I probably, when I started, because  
17 it was a matter of then starting off seeing  
18 patients and gradually as that part of the  
19 practice built up, because there was the ability  
20 for us to see patients, more than just the one  
21 physician, my interest was still strongly to  
22 continue doing both anesthesia and pain  
23 management.

24 So, we kind of shared the case load  
25 for the pain procedures. So it probably started



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Page 28

1 off where I was seeing maybe half a day of pain  
2 patients and just gradually grew a little bit  
3 more.

4 By the time I left there I was  
5 probably doing that anywhere from one to two days  
6 a week.

7 Q. Doing that being?

8 A. Pain management. And then doing  
9 anesthesia.

10 I was still taking calls for the  
11 anesthesia part, which was overnight call at the  
12 hospital, the same as any other member in the  
13 group, and then doing anesthesia in the ORs, the  
14 days I wasn't doing pain management during the  
15 daytime.

16 Q. Okay. And you stayed there for a  
17 little less than three years according to your CV.

18 A. Uh-huh.

19 Q. And moved on to Harford County  
20 Ambulatory Surgery Center.

21 Were you the Director of  
22 Anesthesiology and Pain Management the entire  
23 time you were at Harford County?

24 A. Actually, no. When they hired me at  
25 Harford County Ambulatory Surgery Center it was



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 29

1 to replace an anesthesiologist who was, who had  
2 retired and they had an interim anesthesiologist  
3 who also was close to retiring, so they needed  
4 someone to do anesthesia there.

5 When they hired me to do anesthesia,  
6 I am not sure that they were aware that I was  
7 pain-fellowship trained.

8 And, so that was a, that is  
9 something that evolved a little bit after I had  
10 already joined or started working for them.

11 And as far as the director, I was  
12 the only anesthesiologist there full-time, which  
13 kind of made me director by default.

14 Q. Okay.

15 A. But the pain management part  
16 happened later.

17 Q. So, can you tell me when it was that  
18 you became the director of pain management at  
19 Harford County?

20 A. I couldn't say. I'm not sure if  
21 somewhere in there, I don't know, any kind of  
22 paperwork or something if they have that as  
23 formally identified that I was made director of,  
24 I mean, it started off where they hired me mainly  
25 to be their anesthesiologist. They have two



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 30

1 operating rooms and I was covering those.

2 And, once they realized I had done a  
3 pain fellowship, asked if I had an interest in  
4 seeing pain patients, and I said sure.

5 So, it was my practice eventually  
6 became a little bit similar to what I had done at  
7 Franklin Square Hospital, where I was doing  
8 anesthesia some days and pain other days. Again  
9 started gradually.

10 And then by the time I think I left  
11 them, I was doing about the same, maybe two days  
12 of, two, two a half days of pain management, and  
13 two and a half to three days of anesthesia.

14 Q. Okay. According to your CV you left  
15 there in June of 2008. And that is, and started  
16 Box Hill Surgery Center in July of 2008.

17 A. So, I started my practice in July of  
18 2008.

19 Box Hill Surgery Center --

20 Q. I asked a bad question so let me try  
21 a different thing.

22 You left Harford in June of 2008.

23 A. Yes.

24 Q. Is that correct?

25 A. Yes.



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016**

Page 31

1 Q. In July of 2008, your CV says you  
2 went into private practice, and was Box Hill  
3 Surgery Center an existing entity at that time?

**4**      **A.**      **No.**

5 Q. And did you start Box Hill Surgery  
6 Center?

7 A. I did.

8 Q. And from 2008 to 2012, what was the  
9 business, if you will, of Box Hill Surgery  
10 Center?

11           A. Just Box Hill Surgery Center was  
12 where I was doing, it functioned as a  
13 free-standing ambulatory surgery center where I  
14 was doing probably most of my chronic pain  
15 procedures.

16 Q. Okay. I want to mark as  
17 Exhibit 1055.

18 | (Exhibit Number 1055)

19 marked for identification.)

20 BY MR. ROTH:

Q. And this has been produced to us, it  
has Bates number BHSC 000260.

23 MS. STEINER: Which is the earlier  
24 version of the CV.

25 BY MR. ROTH:



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 32

1           Q.     The version, this is a version of  
2 your CV that was produced to us before today.

3                 Between 2008 and 2012, and I mean  
4 the end of 2012, how much of your practice was  
5 pain management versus, were you doing any  
6 delivery of anesthesia in the operating rooms?

7           A.     I have continued to do anesthesia  
8 the entire time.

9                 Probably varied a little bit over  
10 time when I first started my practice.

11                 I picked up more anesthesia time at  
12 local surgery centers as an independent  
13 contractor.

14                 As the pain practice got more  
15 established, oh, and I was doing anesthesia for  
16 Harford County Ambulatory Surgical Center  
17 part-time also. And then for a period of time it  
18 was fairly steady where I was doing one day of  
19 anesthesia at Harford County Ambulatory Surgical  
20 Center, seeing office patients three, three and a  
21 half days a week and then doing procedures  
22 usually a half to one day a week.

23           Q.     The reason why I showed you the  
24 earlier version of your CV is, it does not have a  
25 section where it says current privileges active



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 33

1 as the one that was provided today does.

2 So, there was no mention today of  
3 active privileges anywhere other than Box Hill.  
4 And on the CV you provided today which was 1054,  
5 you list Harford County Ambulatory Surgical  
6 Center and Surgical Center of White Marsh as  
7 active privilege -- places where you have active  
8 privileges in addition to Box Hill.

9 Did you, before, between 2008 and  
10 the end of 2012, have active privileges for  
11 Harford County Ambulatory Surgical Center and the  
12 Surgical Center of White March?

13 A. Harford County Ambulatory Surgery  
14 Center, yes. Surgical Center of White Marsh was  
15 not open in 2008.

16 Gosh, I'm not sure I remember  
17 exactly when they opened, but I have been going  
18 there, here and there, for at least the last,  
19 off-and-on, the last year or two. They were  
20 not --

21 Q. The last year or two would take us  
22 back to 2014.

23 A. Correct. I don't know if they  
24 existed. Definitely not in 2008 and I'm not sure  
25 if they existed even in 2012.



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 34

1           Q.     And you have a courtesy privilege  
2     listed in your current CV at the University of  
3     Maryland Upper Chesapeake Medical Center and  
4     MedStar Franklin Square Hospital.

5                   What does that mean?

6           A.     Courtesy privileges is where they  
7     have changed the definitions a little bit over  
8     time, the hospitals have.

9                   Currently what that is is I can go  
10    in, have access to a patient record, but I'm not  
11    actively, I don't have privileges to actively  
12    take care of a patient.

13          Q.     Okay. Between 2008 and 20, the end  
14    of 2012, were you seeing patients at Harford  
15    County Ambulatory Surgery Center for pain  
16    management.

17          A.     I did, for approximately a year.  
18    Because I started the pain practice, I actually  
19    got active privileges at Upper Chesapeake, to be  
20    able to, I needed a place to do the procedures.  
21    The office setup was not set up to be able to do  
22    x-ray guided procedures.

23                   So, I requested privileges at Upper  
24    Chesapeake and requested to continue privileges  
25    at Harford County Ambulatory Surgery Center for



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 35

1 pain procedures.

2 I continued going to Harford County  
3 Ambulatory Surgery Center even after Box Hill was  
4 open for pain procedures, because even though, I  
5 guess, doors were opened, the licensure process,  
6 the accreditation, insurance contracts, they took  
7 time.

8 So, for that initial, I'm not sure  
9 exactly dates, but, probably almost a year I was  
10 still doing some of my procedures at Harford  
11 County Ambulatory Surgery Center.

12 Q. Okay. And, not holding you to a  
13 precise time, would it be fair to say that after  
14 July of 2009, say, you were not delivering pain,  
15 I'm sorry, you were not seeing pain management  
16 patients at Harford County?

17 A. Not on a regular basis.

18 Q. Okay. Well then let me, I just want  
19 to be clear.

20 Were there times after that first  
21 year, up to the end of 2012, when you would treat  
22 patients, pain management patients, at Harford  
23 County Ambulatory Center?

24 A. I'm not sure about 2012. But,  
25 somewhere between 2009 and 2012 could I have done



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 36

1       a pain procedure, possible.

2                  If, since I was still doing  
 3     anesthesia there, if there was, I guess, the best  
 4     example that comes to mind off the top of my head  
 5     right now is there was a physician who had seen  
 6     me at Harford County Ambulatory Surgery Center as  
 7     a patient, and he knew I worked at Harford  
 8     County's Ambulatory Surgery Center for  
 9     anesthesia, and I remember him calling me one  
 10   time when I was doing anesthesia there to see if  
 11   I could see him for his pain, for a procedure.

12                  And do it over there because of some  
 13   insurance reason, I'm not sure what it was. But  
 14   it was easier for him to get it done at Harford  
 15   County, and I said yes.

16                  So, I know I still had privileges  
 17   there, but I wasn't routinely going there a  
 18   certain day of the week or routinely doing  
 19   procedures there.

20                  Q.   When you would see patients at  
 21   Harford County, and again if I'm asking this the  
 22   wrong way, you will let me know; I'm sure your  
 23   lawyers will.

24                  But what I'm trying to find out is  
 25   were these patients, were these Harford County



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 37

1 patients or Box Hill patients?

2 A. That is easy to answer. They were  
3 Ritu Bhambhani patients.

4 Q. Okay. Tell me about that.

5 A. So, the pain practice, once I left  
6 Harford County Ambulatory Surgery Center,  
7 patients that I saw were Ritu Bhambhani's chronic  
8 pain patients.

9 Q. Okay.

10 A. A certain percentage of those  
11 patients, if they needed a procedure, had the  
12 option to have it done at Box Hill Surgery  
13 Center, had the option to get it done at Upper  
14 Chesapeake, had the option to get it done at  
15 Harford County Ambulatory Surgery Center, because  
16 I had privileges at all of those places.

17 So any patient that I might have  
18 injected at Harford County Ambulatory Surgery  
19 Center after July of 2008 would have been Ritu  
20 Bhambhani's patient going to Harford County  
21 Ambulatory Surgery Center where they are the  
22 places where it is being done, so there is a  
23 facility where it is being done.

24 But, the provider, the physician  
25 would be Ritu Bhambhani.



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Page 59

1 information about, you know, the equipment that  
2 you would need, the medications you would need,  
3 you know, the stuff you need to run an ambulatory  
4 pain management center?

5 A. Since the purpose of Box Hill was  
6 mainly to do procedures for my patients, and I  
7 have been doing those already at the time for  
8 almost eight years, I didn't necessarily ask of  
9 what I would need.

10 In terms of the question of where,  
11 like I said, I had been using these things at  
12 Harford County, I was still actively providing  
13 care there. So it was fairly simple to ask them.

14 That is a multi-specialty surgery  
15 center providing other services. I was mainly  
16 asking about what I was requiring for my pain  
17 procedures, because I was intending to do similar  
18 procedures as I was there already for years, to  
19 ask where they were getting the supplies from and  
20 I just continued the same.

21 Q. And do you remember who it is that  
22 you spoke to at Harford to get that information?

23 A. For supplies mainly?

24 Q. I'm really thinking now about  
25 medications.



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 60

1           A.     Okay. For medications, mainly, it  
2 would either be Barbara Wagner who does most of  
3 their ordering, or it would be their nurse  
4 manager, Kim Marrow.

5           Q.     And is Barbara Wagner a physician?

6           A.     No, she does their ordering; she is  
7 a surgical tech who is, does most of their  
8 ordering.

9           Q.     Okay. Along the course of your  
10 training in anesthesia and pain management, is  
11 one of the things you learn, you know, about the  
12 actual medications, the agents that provide pain  
13 relief?

14                 MS. STEINER: Objection as to form.  
15 You can answer.

16                 THE WITNESS: I'm not sure I  
17 understand.

18 BY MR. ROTH:

19                 Q.     Sure. I mean, did you receive  
20 training in what types of medications or  
21 compounds worked to provide pain relief?

22                 A.     Where I did my residency and  
23 fellowship?

24                 The best that I remember for almost  
25 the entire time, at least during the fellowship,



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Page 78

1 don't recall making a differentiation at the  
2 time.

3 Q. Okay. Have you, since using,  
4 starting using preservative-free MPA, can you  
5 tell me approximately when that was?

6 A. Sometime when I started doing pain  
7 at Harford County Ambulatory Surgical Center.

8 I would have to guess I started  
9 there in mid-2008. So, sometime around --

10 MS. STEINER: I think you are off.

11 THE WITNESS: Oh, I'm sorry, 2003.

12 So, somewhere between that and 2004.

13 BY MR. ROTH:

14 Q. Okay. And again I was really just  
15 looking for an approximation.

16 A. Right, right, right.

17 Q. Because I wanted to know, since you  
18 began using preservative-free MPA, and by the way  
19 was that always, that was always compounded? The  
20 preservative-free MPA?

21 MS. STEINER: Objection as to  
22 foundation.

23 BY MR. ROTH:

24 Q. Well, was the preservative-free MPA  
25 that you began using a compounded steroid?



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Page 79

1           A.     At Harford County Ambulatory Surgery  
2         Center?

3           Q.     Yes.

4           A.     I know they were getting it from  
5     NECC because that is more so not so much  
6     initially when they first started getting, like I  
7     said I wasn't involved with the process of  
8     getting the medication.

9                   But, more so finding out where they  
10    were getting it from as I was getting ready to  
11    start my practice when, you know --

12          Q.     Understood. So, I was looking back  
13    after your conversation with, I think her name  
14    was Barbara.

15          A.     Yes.

16          Q.     You learned they got their MPA from  
17    NECC?

18          A.     Correct.

19          Q.     And you learned that that was a  
20    compounding pharmacy?

21          A.     Most likely, yes.

22          Q.     Okay. In any event, since you began  
23    using preservative-free MPA, did you do any  
24    research or personal investigation to determine  
25    whether or not steroids that had preservatives in



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Page 81

1           Square, he was there. These were the  
2           steroids available, this is what I used,  
3           okay.

4           Over here, I was not involved in the  
5           ordering process. So, I don't remember  
6           asking about the actual source at the time  
7           when he first -- it probably would have been  
8           more a discussion between him and the person  
9           ordering, or their nurse manager there at the  
10          time.

11 BY MR. ROTH:

12 Q. In 2008 when you became the person  
13 responsible for deciding what medications to  
14 purchase for Box Hill and for your patients --

15 A. Uh-huh.

16 Q. -- until the recall, did you  
17 investigate whether or not there were other  
18 manufacturers of preservative-free MPA than NECC?

19 A. No.

20 Q. Are you aware or were you aware of  
21 whether or not there were any preservative-free  
22 steroids available other than the MPA, I'm sorry,  
23 and let me set my time frame.

24 After you became responsible for  
25 purchasing, for deciding what steroids would be



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Page 82

1 purchased for Box Hill, until the recall, did you  
2 know whether or not there was available  
3 preservative-free steroids other than what you  
4 were purchasing from NECC?

5 A. I had no reason to, or at least the  
6 best that I remember, I don't remember having to  
7 look for another source. I mentioned earlier it  
8 was something that I used for years prior, so it  
9 was a, not just this one thing but most of the  
10 supplies that I got was a simple, kind of thing  
11 to say, okay, this is where they got it from, I  
12 have used this before, I was fine with it and  
13 this is what I'm going to continue using.

14 If I used, like I said anything  
15 other than this, I don't remember having to  
16 either ask Andy or my nurse or me personally  
17 thinking of let me look for an alternative.

18 Q. Okay. And again you say you don't  
19 remember doing it.

20 But, between 2008 and the time of  
21 the recall, was NECC your sole source for  
22 injectable steroids at Box Hill?

23 A. For the most part. The only part I  
24 don't remember, I know somewhere in there, there  
25 were case reports of particulate steroid causing



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 83

1 problems in cervical injections.

2                   What I don't remember is if I had  
3 that discussion with the nurse at Box Hill or  
4 Harford County where I wanted to try a  
5 nonparticulate steroid, and there is only a  
6 couple of different options there that I would  
7 have used that.

8                   But as far as the preservative-free  
9 MPA, the best I know NECC was pretty much our  
10 source the entire time.

11                  Q.     Okay. Let me turn a little bit  
12 about the decision to use NECC.

13                  You said you spoke with Barbara  
14 Wagner at Harford. What do you recall about your  
15 conversation about using NECC?

16                  A.     I wouldn't recall a conversation  
17 from 2008.

18                  The general sense of the time was  
19 getting a list of, you know, okay, she says, you  
20 know, these are the gloves you used to use, this  
21 is the local anesthetic that you have used for  
22 the last five years, this is the skin prep you  
23 have used for the last five years, this is the  
24 steroid you have used, this is the pointers you  
25 use, and getting that list and seeing where she



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 84

1 was getting them from, and, reaching out to the  
2 same providers of the different supplies and  
3 either, you know, me myself, if I had time or  
4 giving it to the nurse and saying research and  
5 I'm going with that.

6 Q. When you first became responsible  
7 for ordering the steroids at Box Hill, other than  
8 saying, asking, I mean, is it basically Barbara,  
9 where did we get the steroids from and she told  
10 you it was NECC and gave you contact information?

11 A. More than likely that is how I would  
12 have, like I said, not just the steroid, that  
13 would have been for pretty much --

14 Q. For everything?

15 A. -- for most supplies that I would  
16 use for the pain procedures.

17 Q. Okay. And when she gave you  
18 information, first of all, when you were at  
19 Harford, had you had any contact with anybody  
20 from NECC?

21 A. Not, to the best of my recollection.

22 Q. Had any, anybody ever talked to you  
23 at all, had you even heard the name NECC before  
24 you asked Barbara where do we get the steroid  
25 from?



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Page 85

1           A.     I mean, if I had, you know, in the  
2 general course of being there five days a week as  
3 their anesthesiologist, but I don't remember  
4 anything out of the ordinary.

5           Q.     Okay. Did you ever get any --  
6 strike that.

7                   In 2008, when you became responsible  
8 for purchasing your medications and steroids and  
9 Barbara tells you okay, we got this stuff from  
10 NECC, did you talk to, did you find out any  
11 information about how NECC, you know, did its  
12 work? Made its compounds?

13               MS. STEINER: Objection as to form  
14 and foundation.

15               THE WITNESS: How they made their  
16 compounds?

17 BY MR. ROTH:

18               Q.     Sure.

19               A.     I was ordering something I had used  
20 before. I have no reason to ask that particular  
21 question of any of the suppliers of any of the  
22 products I was getting at the time because I  
23 wasn't really, in my mind at least I wasn't  
24 changing anything of what I had done at an  
25 established center. They were Medicare certified



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 86

1 state licensed, AAAC accredited, I had done it  
2 for years over there. I was not consciously  
3 making a particular change to look into anything  
4 further about these specific companies, I guess.

5 Q. Okay.

6 A. Process.

7 Q. And, so, all of those things you  
8 were mentioning about they were Medicare  
9 approved, they were AAA, you know, rated, that  
10 related to Harford, right?

11 A. Uh-huh.

12 MS. STEINER: That is a yes?

13 THE WITNESS: Yes, sorry.

14 BY MR. ROTH:

15 Q. So, in a, do I understand then  
16 because they were relying on this, on these  
17 providers, whether it was NECC or others, that  
18 was a good enough reference for you to use those  
19 providers as well when you started your own shop?

20 A. I mean, I had used those things  
21 before.

22 So, the fact that I was at a place  
23 that I had worked at and I had used those  
24 products before for every single thing that I  
25 needed to continue doing pain management, it



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Page 87

1 seemed like a reasonable thing to continue using  
2 the same.

3 Q. What is a compounding pharmacy? I  
4 mean, do you know what a compounding pharmacy is?

5 A. If they have like a legal  
6 definition, I'm not sure.

7 But, my best understanding is it is  
8 a pharmacy that can put together a medication in  
9 a form that a, I guess a regular manufacturing  
10 company does not.

11 Q. Okay. And, do you, did you, between  
12 2008 and the time of the recall, know whether or  
13 not compounding pharmacies were subject to FDA  
14 oversight?

15 A. Since the day I came to the country  
16 I assumed every medicine is under FDA oversight.  
17 So I have to admit I don't recall ever  
18 specifically thinking about the, oversight over  
19 compounding pharmacies specifically.

20 Q. Okay. So, I take it then you were  
21 not aware that compounded drugs don't have FDA  
22 findings of safety, efficacy and manufacturing  
23 quality.

24 MS. STEINER: Objection as to form  
25 and foundation.



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 160

1 Q. 0521. You are 100 percent right.

2 Just to be clear, I got it wrong.

3 A. And the 0521 lot again that was  
4 simple. We had only used it one day and for one  
5 other patient. So, again that was  
6 straightforward.

7 Q. When was the lot 0521 purchased?

8 A. Not purchased from NECC.

9 After I had been contacted by  
10 Mr. Rozek about Mrs. Rozek's passing away, he  
11 had, I think called me on my phone to let me know  
12 that she had passed away.

13 Right around the same time, I am not  
14 sure of the exact dates, again I could look in  
15 charts and be more certain on those. Right  
16 around the same time I had received a call from  
17 Ms. Dreisch that she had been to the hospital a  
18 couple of times. We had done an internal, we is  
19 Andy and I, had sat down and looked at our  
20 internal process. The two patients had presented  
21 at different hospitals, very different  
22 presentations.

23 I had already spoken, when Ms. Rozek  
24 passed away, I had already spoken with a  
25 physician at Johns Hopkins, which was not the



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 161

1 initial hospital where she had been admitted, who  
2 had asked questions about her procedure, whether  
3 there had been anything untoward during the  
4 procedure.

5 I had already looked at my images  
6 that I had saved from her procedure. We usually  
7 save an image, usually when I inject the dye to  
8 confirm needle placement.

9 Just trying to see if there was any  
10 correlation.

11 They, at the time were not sure what  
12 had led to her illness, either her initial  
13 hospital where she was admitted based on what  
14 Mr. Rozek told me or Johns Hopkins, I think I  
15 spoke to the intensivist there.

16 And they were just looking at all  
17 different aspects I guess, of her health prior  
18 to that. And since the injection was something  
19 that had happened a couple of weeks prior to her  
20 being sick.

21 And then on the other side was  
22 Ms. Dreisch, very different presentation,  
23 different hospital, being treated for a very  
24 different kind of symptom complex.

25 We just said because those were two



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 162

1 patients who had had injections, Andy and I sat  
2 down and just did an internal kind of thorough  
3 review of our process to see was there anything  
4 that we could identify that could tie those two  
5 patients to their procedures.

6 And, not being able to explain,  
7 based on anything that Ms. Dreisch had told me or  
8 Mr. Rozek or the intensivist, we just sat down  
9 and just kind of reviewed our process from the  
10 time the patient walks in the door until the time  
11 they leave. Everything that happens to them, who  
12 all takes care of them, and we just decided we  
13 were just going to maybe look at, is there  
14 something else that we can do.

15 We could not figure out at that  
16 point any correlation with the procedure. At  
17 least we didn't have an explanation, none of the  
18 other providers seemed to.

19 We decided, you know, if it was  
20 somehow related to something that happened here,  
21 is there anything else we could do? And the one  
22 thing that came to mind was, well as we order  
23 supplies, not knowing what it was, I told Andy,  
24 let's reorder all of our injectables and anything  
25 that is sterile, you know, gloves, their skin



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 163

1 prep, what have you, and make sure no one had  
 2 been sick on our staff recently.

3                 Because one of the things that  
 4 Ms. Dreisch's initial working diagnosis that she  
 5 was being treated for, that she had told us was a  
 6 viral meningitis, which is usually community  
 7 acquired.

8                 So, I couldn't come up with anything  
 9 there.

10                So, thinking of that kind of a  
 11 transmission, I started asking all of my staff to  
 12 start wearing a mask if they were going to be in  
 13 the operating room. Prior to that I used to wear  
 14 a mask. I started saying well everyone wear a  
 15 mask.

16                So, coming to the 0521, it wasn't  
 17 ordered from NECC. I found out about Ms. Rozek's  
 18 passing away, whatever day. Andy said okay, I  
 19 will place a new order, then came back and said  
 20 well they are not going to be able to get it to  
 21 us prior to a certain date. You have a procedure  
 22 day before that. So, I reached out to Harford  
 23 County Ambulatory Surgery Center where I was  
 24 still doing anesthesia, and asked if we could  
 25 borrow medication from them.



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 164

1                   I borrowed that 35 vials off that  
 2 lot number and used it for, I think, 24 patients  
 3 one day and one other patient another day while  
 4 we placed our own order, the 21st. So, the  
 5 procedure is done on the 21st were done using  
 6 this medication, the 0521 lot that was borrowed  
 7 from Harford County.

8                   Q.     That procedure was done on  
 9 September 21st?

10                  A.     Correct.

11                  Q.     Were done using 0521 2012.

12                  A.     Right. And even earlier in that  
 13 week, if I remember, there might have been one  
 14 procedure on a day. Because, that was a few days  
 15 after the 17th. On the 17th already, the 17th is  
 16 when I found out about her passing away. I  
 17 talked to Andy probably right away or the next  
 18 day and said let's figure something out. Let's  
 19 sit down and go over everything. I'm going to  
 20 say that it was probably later that day on the  
 21 17th.

22                  And, when we started talking about,  
 23 okay, what are the different things we are going  
 24 to do, and we decided we are going to order the  
 25 21st was a regular procedure day.



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 165

1                   So, by the 18th, 19th, he is like,  
 2 okay, well, we will order the next lot in the  
 3 meantime let's use, if we can borrow it from  
 4 Harford County, so that is what we borrowed from  
 5 them.

6                   Q.     Okay. The, did you know when you  
 7 contacted Harford that the MPA, the preservative-  
 8 free, you asked for preservative-free MPA?

9                   A.     That is what they were using at the  
 10 time. So I asked for it.

11                  Q.     So, you were, you knew that you were  
 12 using NECC provided MPA?

13                  A.     Yes.

14                  Q.     Okay. Did you call NECC after your  
 15 November, September 17th when you had this  
 16 meeting with Andy and before you got the notice  
 17 of recall?

18                  A.     I didn't call NECC or any of the  
 19 others. Like I said, at the time it was more  
 20 just trying to come up with any way to correlate  
 21 or to explain what those two patients were going  
 22 through or had gone through.

23                  And, figuring out was there anything  
 24 in our process, not just a medicine, not an  
 25 injection, but just our whole, like I was even



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016**

Page 183

(Whereupon, the record was read by  
the reporter as requested.)

8 MS. STEINER: Objection as to form  
9 and foundation.

10 BY MR. ROTH:

11 Q. Yes, so let me try to rephrase the  
12 question so it is a little less glib.

13                   But, since the recall, have you  
14 learned ways that you as a physician can, you  
15 know, verify whether or not a compounding  
16 pharmacy is utilizing good manufacturing  
17 processes?

18 MS. STEINER: Objection as to form  
19 and foundation.

20                   THE WITNESS: Generally speaking,  
21                   right after the recall which happened on the  
22                   26th or the 27th of September, incidentally I  
23                   used to do anesthesia on Wednesday at Harford  
24                   County Ambulatory Surgical Center.

25 The room that I was doing anesthesia



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 184

1       in, I think had the surgical tech who orders  
 2       medications there, had mentioned, I had not  
 3       seen the recall notice at this point, this  
 4       was a Wednesday during the day, had mentioned  
 5       that they were planning on switching, getting  
 6       preservative-free MPA from another pharmacy.

7           So, when the recall notice first  
 8       came, besides other things, but the decision  
 9       to get the steroid from another place at the  
 10      time of the recall, and not still getting any  
 11      indication from NECC based on my call to them  
 12      when I saw the recall notice, whether there  
 13      had been any problems.

14           I was still with the thought  
 15      preservative-free was the best steroid to use  
 16      for patients for their spinal injections. So  
 17      I had still intentions to continue using  
 18      preservative, obviously they were not  
 19      supplying it.

20           And since I had just the previous  
 21      day spoken with the person at Harford County  
 22      that they were switching, I said, oh, this is  
 23      a coincidence. Otherwise I would have no  
 24      idea, since the recall, since I have never  
 25      ordered from anywhere else, that it did make



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 185

1 it easier for me to actually have another  
2 resource already, that I could just call her  
3 and get the information on who they were  
4 going with.

5 I hadn't really paid that much  
6 attention the day before when she said they  
7 were switching, because I had no thoughts of  
8 switching until that recall notice came.

9 So, I asked her to give me the name  
10 of the contact person for the new pharmacy  
11 they were going with.

12 And, I don't remember if I  
13 personally called or if Andy called  
14 requesting that an account be set up for us  
15 to be able to order from them.

16 I saw the recall notice on a  
17 Thursday; I still had procedures to do that  
18 Friday. I could not use what I had on hand  
19 from the 0629, since I had already decided  
20 not to use that and had borrowed the 0521  
21 from Harford County which was also on the  
22 recall notice, so I couldn't use that.

23 The 0810 that had been shipped by  
24 then was on the recall notice; I couldn't use  
25 that.



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 186

1                   So, again, I don't remember if I  
2                   called or I asked Andy to call, you know,  
3                   Barbara had mentioned they were switching,  
4                   had they switched already and do they have  
5                   something else on hand.

6                   They happen to have JCB's  
7                   preservative-free MPA.

8 BY MR. ROTH:

9 Q.               Whose was it?

10 A.               Harford County, JCB Labs, they  
11               happened to have that already on hand, so we  
12               borrowed that to get through my procedures on the  
13               28th.

14                   There was the weekend, October 1st  
15               is when I got the call from the Department of  
16               Health.

17                   Still not understanding the extent  
18               of NECC's problem, I said okay, while we started  
19               to do what the Department of Health wanted us to  
20               do, still under the impression it was an isolated  
21               NECC problem not a, some sort of a bigger  
22               compounding pharmacy's kind of an issue. As we  
23               were doing what they needed us to do with these  
24               patients --

25 Q.               And that is the calling and



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 187

1 notifying?

2           A. Exactly. Calling, notifying, giving  
3 them information until they told us that we could  
4 start calling or sending letters.

5           To come back to your question, did I  
6 know any different on what to ask? So I again  
7 reached back to Barb.

8           At the time she had informed me that  
9 they had a pharmacy consultant that they could  
10 reach out to as needed.

11          And I said, hey, as he suggested,  
12 there is something I should be asking this new  
13 place now that I'm getting this medication from.

14          And I think she gave me a list,  
15 either of questions to ask or asking for their  
16 license.

17          So, whatever I must have asked based  
18 on that pharmacist suggesting to Barb, Barb  
19 passing that information to me, I asked all of  
20 that of JCB. Kept it, I have a JCB folder, all  
21 of that stuff will be in there.

22          However, what changed my mind in  
23 thinking there was anything I could do to confirm  
24 that what they were giving me was sterile and  
25 what I expected it to be, changed over the



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VIDEOTAPED DEPOSITION OF RITU T. BHAMBHANI, M.D. on 02/10/2016

Page 188

1 subsequent months as I saw either news or other  
2 recall reports from other compounding pharmacies  
3 having contamination in their products.

4 So, within those first few months, I  
5 did use the JCB product that we initially  
6 ordered.

7 But as I continued to see the news  
8 reports of the other, in other states compounding  
9 pharmacies having issues, at the time I had  
10 decided since there is no way for me to ensure or  
11 oversee or check what they were doing is right.  
12 And clearly the people who are supposed to be  
13 making sure what they were doing they are doing  
14 right, I have no control of either, that my then  
15 safest option at the time was to use steroid with  
16 preservative.

17 And I switched to using preservative  
18 methylprednisolone.

19 Q. Do you remember the name of the  
20 consultant that Barb suggested you speak with?

21 MS. STEINER: Objection as to  
22 foundation.

23 THE WITNESS: I'm sorry, she did not  
24 suggest I speak, that is a resource that they  
25 had that she had already spoken with.



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